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September 28, 2007

**VIA ELECTRONIC MAIL AND POSTAL
SERVICE**

Ms. Marlene H. Dortch
Secretary
Federal Communication Commission
445 12th Street, S.W.
Washington, D.C. 20554

FILED/ACCEPTED
SEP 28 2007

Federal Communications Commission
Office of the Secretary

Re: *Ex Parte Notice*
Investigation of the Spectrum Requirements for Advanced Medical Technologies
ET Docket No. 06-135

Dear Ms. Dortch:

On September 26, 2007, Perry Mills, Vice President and Chief Technology Officer of Transoma Medical, Inc. ("Transoma"), and the undersigned met with the following representatives of the Office of Engineering and Technology ("OET"): Julius Knapp, Chief; Bruce Romano, Associate Chief (Legal); Geraldine Matise, Chief, Policy and Rules Division; and Jamison Prime, Spectrum Policy Branch Chief. The subject of the meeting was the positions taken by Transoma in its letter to the Commission filed in this proceeding on August 23, 2007. The issues outlined by Transoma at the meeting, as updated to reflect the discussion held, are summarized in the attached PowerPoint presentation given by Mr. Mills.

In response to a question at the meeting regarding telemetry users' need to cohabitate research subjects, this requirement in part originates from the following two sources:

° In the United States, Guide to the Care and Use of Animals (1966), found at <http://grants.nih.gov/grants/olaw/olaw.htm>.

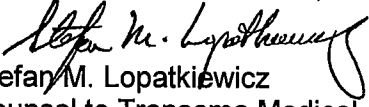
° In Europe, Species-specific documents found under the European Treaty Series ETS-123, which are available at www.coe.int.

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Pursuant to Section 1.1206 of the Commission's Rules, 47 C.F.R. § 1.1206, this letter is being filed electronically with the Office of the Secretary. Please direct any questions regarding this matter to the undersigned.

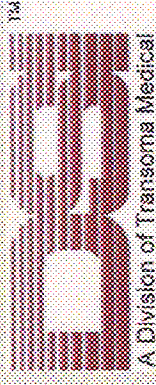
Sincerely yours,



Stefan M. Lopatkiewicz
Counsel to Transoma Medical, Inc.

Attachment

cc: Julius Knapp, Chief
Bruce Romano
Geraldine Matise
Jamison Prime



Medical Implant Communications Service (MICS) and the MedRadio Proceeding

Transoma Medical Inc./ Data Sciences International
September 28, 2007

Agenda

Expansion of permissible forms of communication in the MedRadio service

- Please ask questions at any point
- Potential addition to permissible communications
- Company background
- Business and products
- Product benefits
- Additional customer needs
- Frequency band availability
- Compatibility of proposal with MICS
 - Separate environment of use
 - Common requirements
- Proposal / Questions

MedRadio Permissible Communications

- **CURRENT MICS PERMISSIBLE COMMUNICATIONS (Sec 95.1209 (a))**
 - Must transmit only operational, diagnostic, and therapeutic information.
 - Must be associated with medical implant device
 - Device must be implanted by a duly authorized health care professional
- **POSSIBLE ADDITION to PERMISSIBLE COMMUNICATIONS**
 - May communicate in a laboratory environment
 - to monitor a research subject for the purpose of improving human health.
 - such as for the development of pharmaceuticals, medical devices, and surgical techniques.

Transoma/DSI Background

- Data Sciences International (DSI) was founded in 1984.
- DSI pioneered the use of implantable wireless devices for monitoring and collecting physiological data in biomedical research.
- DSI has established 80% market share in chronic animal monitoring.
- DSI is a division of Transoma Medical. The Transoma Medical name was created in 2003 associated with development of human clinical diagnostic systems.
- DSI (biomedical research) website is www.datasci.com.
- Transoma (human diagnostic) website is www.transomamedical.com.

DSI Business

- **Corporate Purpose:** Improve health and quality of life by applying technology to medicine.
- **Product:** Implantable biomedical telemetry and associated data acquisition equipment and software.
- **Customers:**
 - Industry – Pharmaceutical, Medical device
 - Contract Research Organization (CRO's)
 - Academic
 - Government
- The top 20 Pharma / CRO's are all DSI customers

Unique Benefit of Telemetric Monitors

- Testing involving vital sign measurements on laboratory animals is required by FDA for nearly EVERY drug.
- Implantable devices can provide better information resulting in new life-saving drugs getting to market faster.
- Monitoring via telemetry is recommended by FDA and American Heart Association guidelines.
- Advantage over traditional approaches:
 - Animals are less stressed providing more accurate data.
 - *Reduction in animal use up to 90% by:
 - Reusing animals in multiple studies.
 - Use of randomized blocking studies (animals are own controls).
 - Eliminating studies by collecting more parameters at once.

* (Kramer K and Kinter L.B. Review: Radiotelemetry in Small Laboratory Animals. *Physiol Genomics* 13:197-205, 2003.)

DSI Product Areas of Use

- The primary use of DSI telemetry is testing the safety and efficacy of experimental pharmaceuticals.
- Safety testing is comprised of the “Core Battery” of tests in the following areas as required by the FDA:
 - Cardiovascular
 - Neuroscience
 - Respiratory

DSI Market Segmentation

The "Core Battery" is Above the Dotted Line...

Research Models	Organization Types	Research Arenas
<ul style="list-style-type: none"> ▪ Extra Small (e.g. Mouse) ▪ Small / Medium (e.g. Rat, Rabbit) ▪ Large (e.g. Dog, Primate) 	<ul style="list-style-type: none"> ▪ Industrial ▪ Contract Research ▪ Academic ▪ Government 	<ul style="list-style-type: none"> ▪ Cardiovascular ▪ Neuroscience / CNS ▪ Respiratory ----- ▪ Renal ▪ Gastro / Intestinal ▪ Ocular ▪ Cancer ▪ Drug Dependence ▪ Metabolism ▪ Urology ▪ Immune ▪ Other...

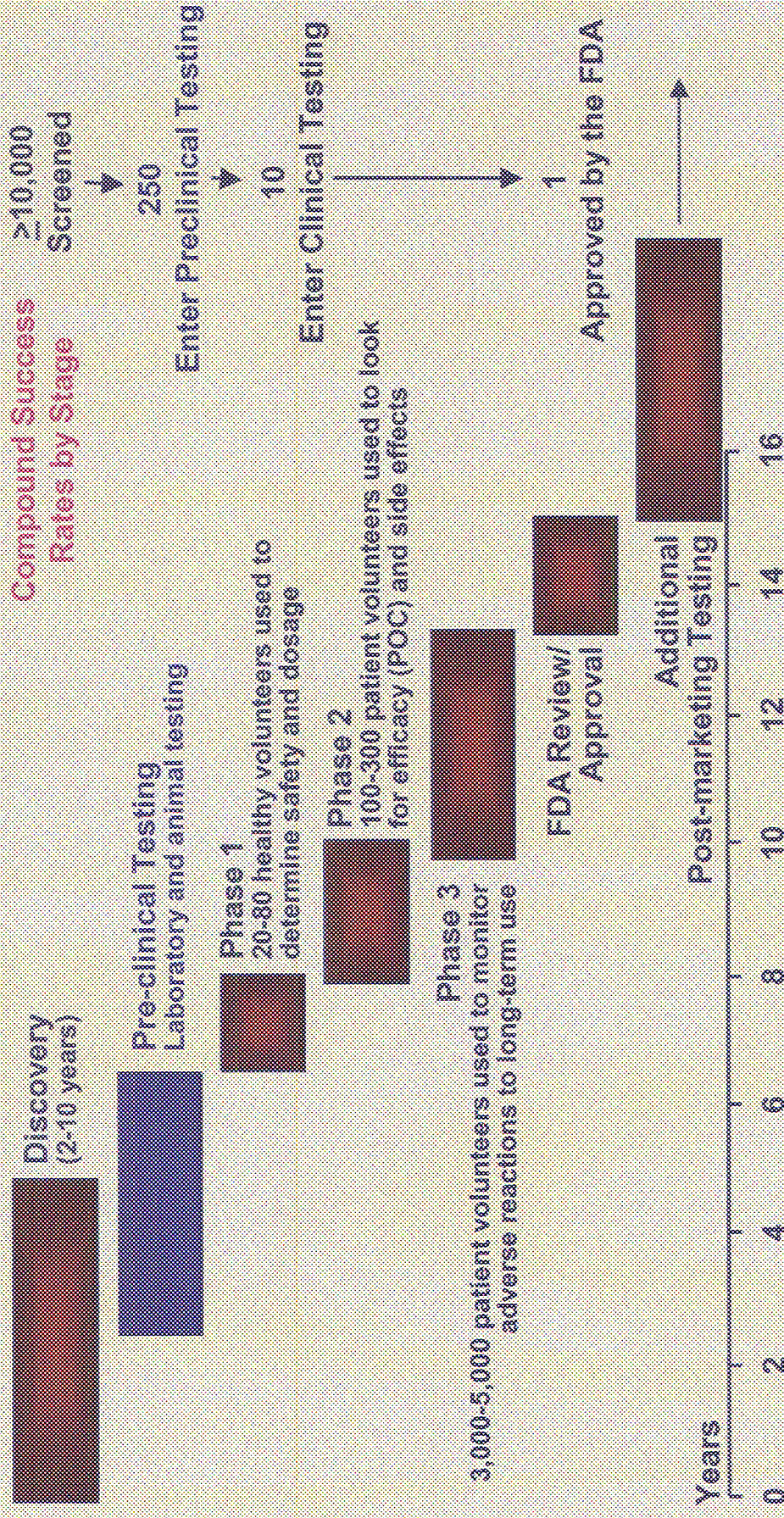
Therapeutic Applications

Research Arenas
▪ Cardiovascular
▪ Neuroscience / CNS
▪ Respiration

▪ Renal
▪ Gastro / Intestinal
▪ Ocular
▪ Cancer
▪ Metabolism
▪ Urology
▪ Drug Dependence
▪ Immune

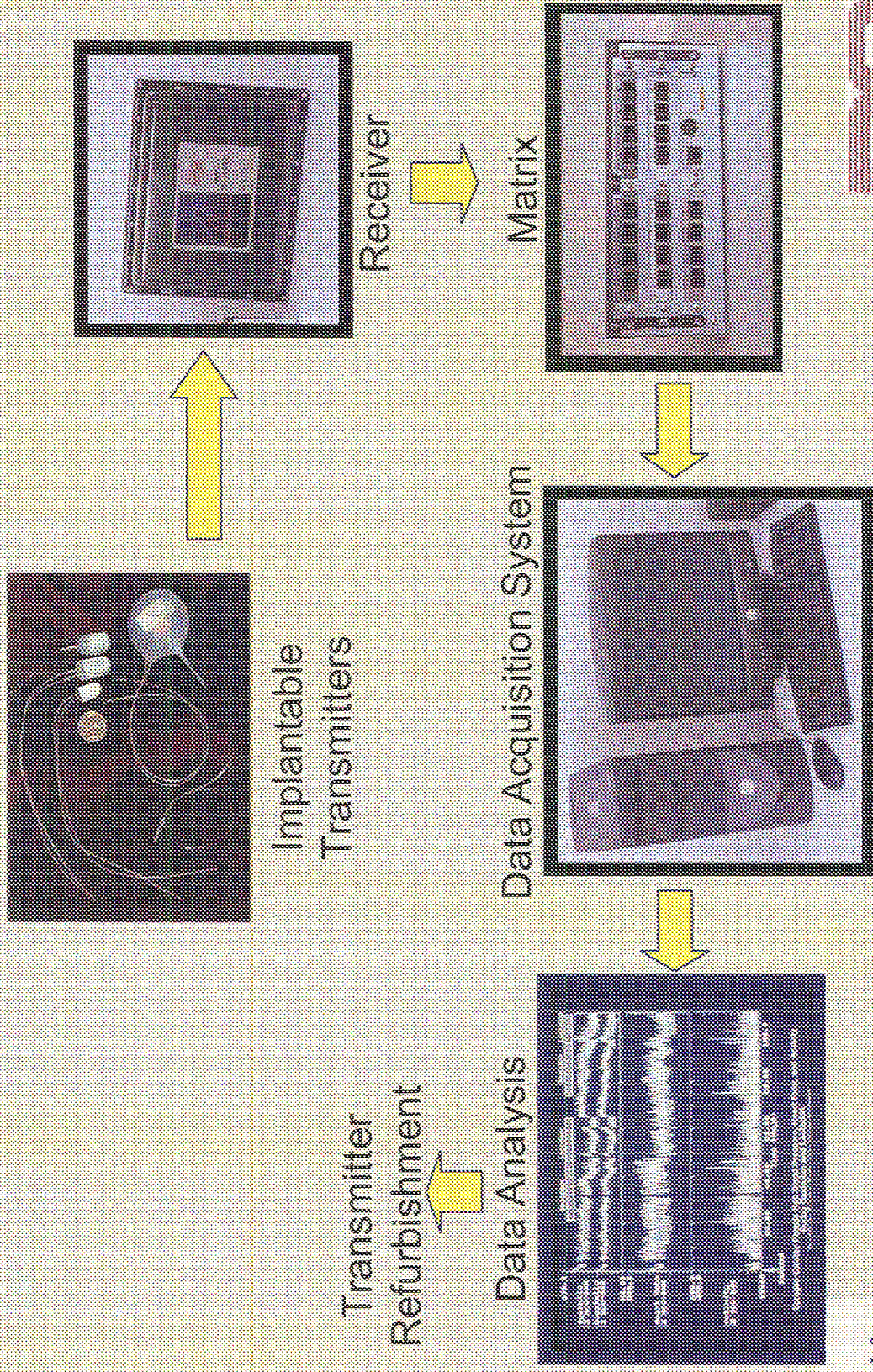
Therapeutic Applications
Anxiety
Attention Deficit
Bipolar
Cognition
Coma
Depression
Epilepsy / Seizure
Pain
Parkinson's
Schizophrenia
Sleep Disorders
Etc...

Drug Compound Success Rates by Stages



Source: Center for the Study of Drug Development, Tufts University

The Current DSI Telemetry System



Additional Customer Needs

- Most DSI Telemetry currently uses a near-field emission at 455KHz.
 - This telemetry satisfies the Part 15.201 criteria of <490KHz and 40dB below 15.209. Transmission is simplex.
- Customers also want the following enhancements:
 - Ability to monitor multiple subjects cohabiting one cage.
 - Full traceability to data source (Digital ID).
 - More parameters, greater signal bandwidth.
 - Reconfigurable for multiple studies, longer battery life.
- Which require:
 - Greater telemetry range (for larger cages housing multiple subjects).
 - Improved data integrity with redundancy and error correction.
 - Simultaneous multiple channels with duplex operation.
 - Higher data throughput – greater spectrum bandwidth.

ISM Band Limitations

- For lab animal telemetry systems that now need greater range and spectrum bandwidth, a higher frequency such as the 902-928MHz ISM band might be a choice.
- The lab animal environment tends to be a high tech, automated environment for reasons of security, environmental control, and the huge volume of data that is generated.
- This environment is likely to include wireless devices such as RFID, network links, wireless keyboards and mice, security alarms, video-monitors, voice links such as telephones, intercoms and headsets, and environmental monitors such as thermometers.
- These devices have the potential to create an adverse environment for an ISM-based biomedical telemetry system.

Limitations for other Bands

- Part 15 Biomedical Telemetry (15.241 and 15.242)
 - Approvals no longer being granted in these bands per 15.37(i).
- 15.231 Periodic operation ... Above 70MHz
 - Data communication is only permitted under a very low power provision (15.231 (e)) which would restrict telemetry range.
 - Duty cycle for 15.231 (e) is required to be < 1:30 which would not satisfy data throughput requirements.
- WMTS Part 95, Subpart H (608-614, 1395-1400, 1427-1429.5 MHz)
 - Limited to operation within health-care facilities.

Interference Mitigation

- The following typical locations for animal telemetry use are separate from those where Human MICS telemetry is used.
 - Pharmaceutical or medical device industry laboratory.
 - Contract research organization laboratory.
 - Government research laboratory.
 - Academic research laboratory.
- Human access to animal labs is tightly controlled for reasons of security, confidentiality, health, and data quality.
- For example, DSL employees are oftentimes not allowed access to locations where DSL equipment is used.
- In industry and government, security is extended to the facility perimeter.

Additional Interference Mitigation

- Any equipment developed under this proposal would be fully compliant with Part 95, Subpart I including LBT and AFA.
- Should there be patients with ambulatory use of MICS telemetry working in an animal facility, LBT and AFA technology would allow compatibility. There would be many channels available since only one MedRadio channel would be needed to handle the data generated by all research subjects within a given area.
- Telemetry range requirements for lab animal telemetry and current MICS applications are very similar (~2meters).
- It is becoming common for animal housing rooms to be rf-shielded due to interference concerns.
- Separate environment, low proliferation (at any given time in the US, ~2600 implants active at ~300 locations).

Compatibility Summary

Human and Animal Telemetry

- Environments-of-use are separate.
- Both applications benefit human health.
- Technical requirements are similar.
 - Implanted Device
 - Optimal frequency choice is the same (compromise of tissue attenuation and antenna efficiency)
 - Implant-to-External link is used for biomedical data.
 - External-to-Implant link is used for low-duty-cycle communication involving configuration, control, and data acknowledgment.
 - The telemetry range requirement is similar

Proposal Regarding MedRadio Permissible Communications

- **CURRENT PERMISSIBLE COMMUNICATIONS (Sec 95.1209 (a))**
..... medical implant programmer/control transmitters may transmit only operational, diagnostic and therapeutic information associated with a medical implant device that has been implanted by a duly authorized health care professional.

- **PROPOSED ADDITION to PERMISSIBLE COMMUNICATIONS**
Devices in the MedRadio service may communicate within a laboratory environment to monitor research subjects for the purpose of improving human health, such as for the discovery, development, and testing of pharmaceuticals, medical devices, and surgical techniques.

- Questions